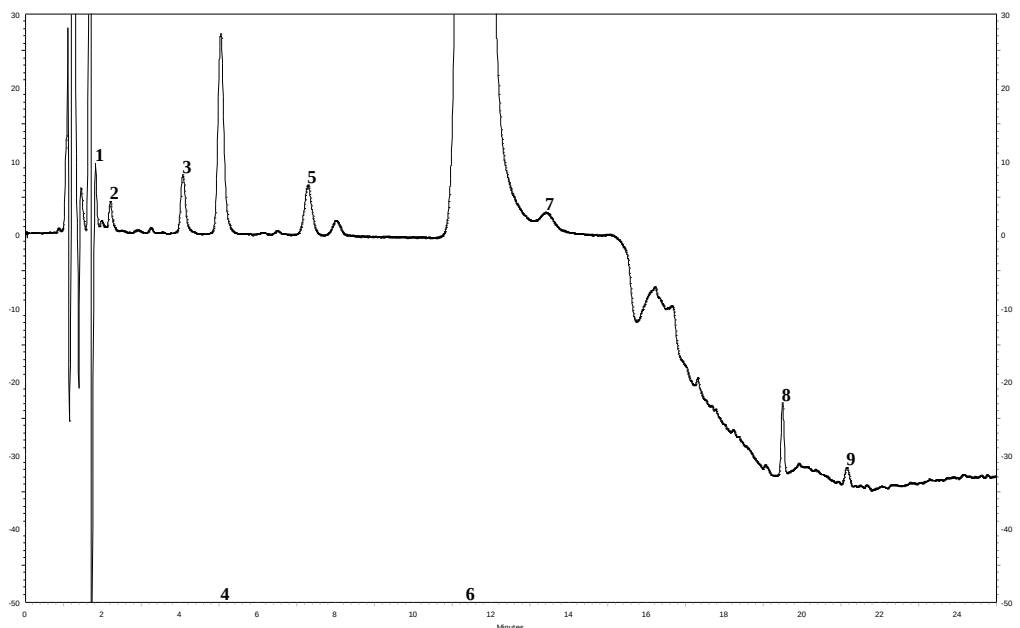




## Clindamycin Vaginal Cream – BP 2021

These chromatograms are provided for information only as an aid to analysts and are intended as guidance for the interpretation and application of BP monographs.

Typical chromatogram for solution (3) in the Related Substances test for Clindamycin Vaginal Cream as published in BP 2021.



Peak ID: 1: Impurity F; 2: Impurity G; 3: Impurity I; 4: Impurity B; 5: Impurity L; 6: Clindamycin phosphate; 7: Impurity J; 8: Impurity E; 9: Impurity K

Column : Waters, Symmetry C18 (150 mm x 4.6 mm, 5 µm)  
Method Ref. : Related substances for the Clindamycin Vaginal Cream monograph from BP 2021

Mobile Phase A : Acetonitrile : Buffer (21:79, v/v)  
Mobile Phase B : Buffer : acetonitrile (40:60, v/v)  
Buffer : 1M potassium dihydrogen phosphate adjusted to pH 6.0 with a 45% w/v solution of potassium hydroxide

|          |                |                        |
|----------|----------------|------------------------|
| Gradient |                |                        |
|          | Time (minutes) | Mobile phase A (% v/v) |
|          | 0 - 13         | 100                    |
|          | 13 - 18        | 100 - 50               |
|          | 18 - 39        | 50                     |
|          | 39 - 45        | 50 - 100               |
|          | 45 - 50        | 100                    |

|  |                        |
|--|------------------------|
|  | Mobile phase B (% v/v) |
|  | 0                      |
|  | 0 - 50                 |
|  | 50                     |
|  | 50 - 0                 |
|  | 0                      |

Diluent : Acetonitrile : water, previously adjusted to pH 2.0 with phosphoric acid (15 : 85, v/v)

Flow rate : 1.1 mL/min

Column Temp : 30 °C

Autosampler : 4 °C

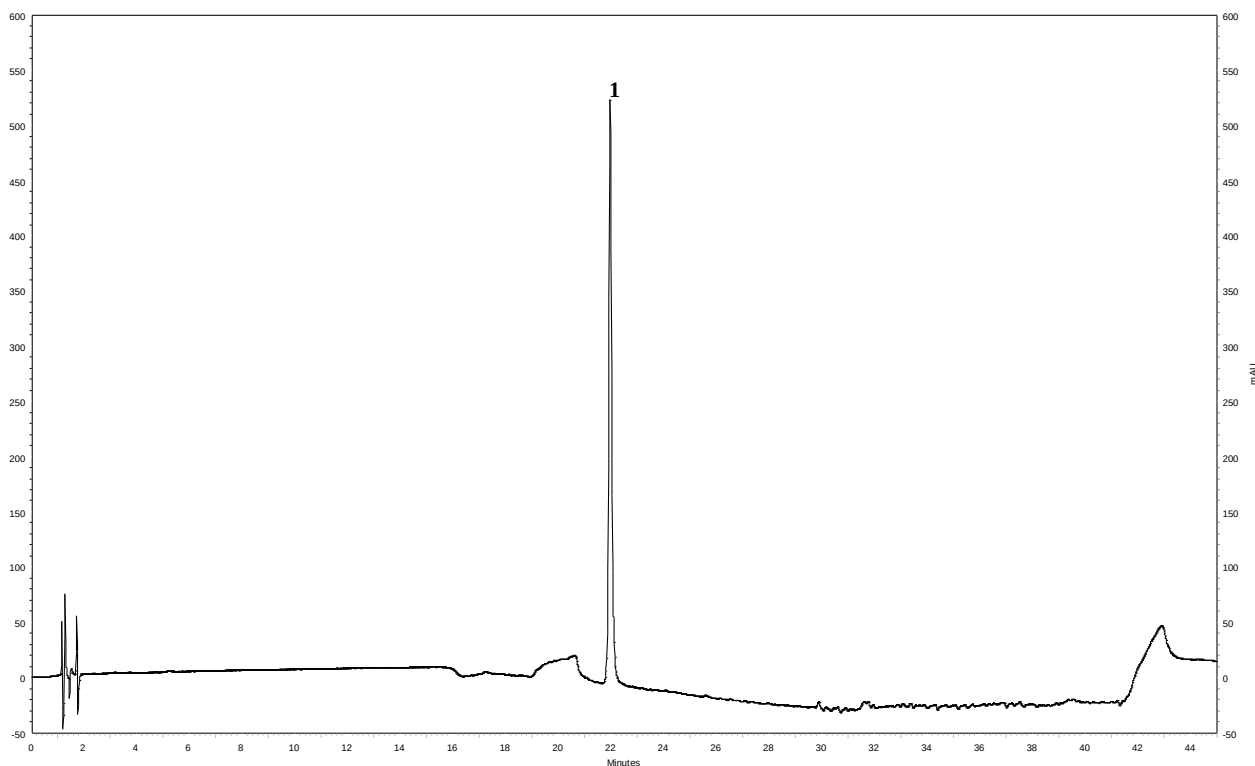
Temp

Injection Volume : 20 µL

Detection : 210 nm



Typical chromatogram for solution (2) in the Assay test for Clindamycin Vaginal Cream as published in BP 2021.



Peak ID: 1: Clindamycin phosphate

Column : Waters, Symmetry C18 (150 mm x 4.6 mm, 5 µm)  
Method Ref. : Assay for the Clindamycin Vaginal Cream monograph from BP 2021  
Mobile Phase A : Acetonitrile: Buffer (15: 85, v/v)  
Mobile Phase B : Buffer : acetonitrile (40:60, v/v)  
Buffer : 1M potassium dihydrogen phosphate adjusted to pH 6.0 with a 450 g/L solution of potassium hydroxide

| Gradient       | :                      | <table><tr><th>Time (minutes)</th><th>Mobile phase A (% v/v)</th><th>Mobile phase B (% v/v)</th></tr><tr><td>0 - 13</td><td>100</td><td>0</td></tr><tr><td>13 - 30</td><td>100 - 44</td><td>0 - 56</td></tr><tr><td>30 - 40</td><td>44</td><td>56</td></tr><tr><td>40 - 41</td><td>44 - 100</td><td>56 - 0</td></tr><tr><td>41 - 45</td><td>100</td><td>0</td></tr></table> | Time (minutes) | Mobile phase A (% v/v) | Mobile phase B (% v/v) | 0 - 13 | 100 | 0 | 13 - 30 | 100 - 44 | 0 - 56 | 30 - 40 | 44 | 56 | 40 - 41 | 44 - 100 | 56 - 0 | 41 - 45 | 100 | 0 |
|----------------|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------------|------------------------|--------|-----|---|---------|----------|--------|---------|----|----|---------|----------|--------|---------|-----|---|
| Time (minutes) | Mobile phase A (% v/v) | Mobile phase B (% v/v)                                                                                                                                                                                                                                                                                                                                                      |                |                        |                        |        |     |   |         |          |        |         |    |    |         |          |        |         |     |   |
| 0 - 13         | 100                    | 0                                                                                                                                                                                                                                                                                                                                                                           |                |                        |                        |        |     |   |         |          |        |         |    |    |         |          |        |         |     |   |
| 13 - 30        | 100 - 44               | 0 - 56                                                                                                                                                                                                                                                                                                                                                                      |                |                        |                        |        |     |   |         |          |        |         |    |    |         |          |        |         |     |   |
| 30 - 40        | 44                     | 56                                                                                                                                                                                                                                                                                                                                                                          |                |                        |                        |        |     |   |         |          |        |         |    |    |         |          |        |         |     |   |
| 40 - 41        | 44 - 100               | 56 - 0                                                                                                                                                                                                                                                                                                                                                                      |                |                        |                        |        |     |   |         |          |        |         |    |    |         |          |        |         |     |   |
| 41 - 45        | 100                    | 0                                                                                                                                                                                                                                                                                                                                                                           |                |                        |                        |        |     |   |         |          |        |         |    |    |         |          |        |         |     |   |

Diluent : Acetonitrile : water, previously adjusted to pH 2.0 with phosphoric acid (15 : 85 v/v)

Flow rate : 1.1 mL/min

Column Temp : 30 °C

Autosampler Temp : 4 °C

Injection Volume : 20 µL

Detection : 210 nm